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Date

June 15, 2006

PTO/SB/21 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE TO TRADE nder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/574,163 TRANSMITTAL Filing Date June 15, 2006 First Named Inventor **FORM** LIU, Jin Art Unit TBD **Examiner Name** TBD (to be used for all correspondence after initial filing) Attorney Docket Number 8028-005-US Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Identify Terminal Disclaimer Extension of Time Request below): Request for Refund Express Abandonment Request 1. Self-addressed, stamped postcard 2. Forms PTO/SB/08A & B CD, Number of CD(s) Information Disclosure Statement 3. Copies of reference as cited Landscape Table on CD Remarks Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Catalyst Law Group, APC Signature Printed name Michael B. Farber, Esq.

CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: Signature Date June 15, 2006 Sara Hare Typed or printed name

Reg. No.

32,612

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Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/574,163			
Filing Date	June 15, 2006			
First Named Inventor	LIU, Jin			
Art Unit	TBD			
Examiner Name	TBD			
Attorney Docket Number	8028-005-US			

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		^{US-} 5,665,589	09-09-1997	HARRIS et al.	
		^{US-} 6,046,050	04-04-2000	STRAUSS et al.	
		^{US-} 6,107,043	08-22-2000	JAUREGUI et al.	
		^{US-} 6,653,105	11-25-2003	TRIGLIA et al.	
		^{US-} 2002/0045262	04-18-2002	PRACHUMSRI	
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		FORE	IGN PATENT DOCU	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
·		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY	,,,	Or Relevant Figures Appear	T ⁶
	L	WO 99/55853	11-04-1999	FUKAYA et al.		
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO Application Number 10/574,163 Filing Date INFORMATION DISCLOSURE March 29, 2006 STATEMENT BY APPLICANT First Named Inventor LIU, Jin **Art Unit TBD** (Use as many sheets as necessary) **Examiner Name TBD** Attorney Docket Number Sheet 3 of 8028-005-US

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		J.B. MILLS et al., "Induction of Drug Metabolism Enzymes and MDR1 Using a Novel Human Hepatocyte Cell Line," J. Pharm. Exp. Therap. 309: 303-309 (2003).	}
		G. LUO et al., "CYP3A4 Induction by Drugs: Correlation Between a Pregnane X Receptor Reporter Gene Assay and CYP3A4 Expression," Drug Metab. Dispos. 30: 795-804 (2002).	
		A. MADAN et al., "Effects of Prototypical Microsomal Enzyme Inducers on Cytochrome P450 Expression in Cultured Human Hepatocytes, Drug Metab. Dispos. 31: 421-431 (2003).	
		G.T. TUCKER et al., "Optimizing Drug Development: Strategies to Assess Drug Metabolism/ Transporter Interaction Potential – Toward," Pharmaceutic. Res. 18: 1071-1080 (2001).	
		T.D. Bjorsson et al., "The Conduct of in Vitro and in Vivo Drug-Drug Interaction Studies: A PhRMA Perspective," J. Clin. Pharmacol. 43: 443-469 (2003).	
	-	F. Bost et al., "Inter-Alpha-Trypsin Inhibitor Proteoglycan Family-a Group of Proteins Binding and Stabilizing the Extracellular Matrix," Eur. J Biochem. 252: 339-346 (1998).	
		S. Yang et al., "Administration of Human Inter-•-Inhibitors Maintains Hemodynamic Stability and Improves Survival During Sepsis," Crit. Care Med. 30: 617-22 (2002).	
		K.E. Thummel & G.R. Wilkinson, "In Vitro and In Vivo Drug Interactions Involving Human CYP 3A," Ann. Rev. Pharmacol. Toxicol. 38: 389-430 (1998).	
		S. M. Cascio, "Novel Strategies for Immortalization of Human Hepatocytes," Artificial Orgs. 25: 529-538 (2001).	
		T. Kuroki & N. Huh, "Why Are Human Cells Resistant to Malignant Cell Transformation in Vitro?," Jpn. J. Cancer Res. 84: 1091-1100 (1993).	

Examiner	Date	-
Signature	 Considered	

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¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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Substitu	ite for form 1449/PTO			Complete if Known		
	10 10 10 11 14 10 11			Application Number	10/574,163	
			SCLOSURE	Filing Date	March 29, 2006	
STA	ATEMENT E	BY A	PPLICANT	First Named Inventor	LIU, Jin	
	(Use as many she	ets as r	necessary)	Art Unit	TBD	
	(occ to many one	,010 40 7		Examiner Name	TBD	
Sheet	2	of	3	Attorney Docket Number	8028-005-US	

		NON PATENT LITERATURE DOCUMENTS	
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		H. ZUR HAUSEN, "Oncogenic Herpesviruses" in J. Tooze ed., DNA Tumor Viruses (Rev. Ed. 2, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1981), pp 747-798.	
		M. POPOVIC et al., "Transformation of Human Umbilical Cord Blood T-Cells by Human T-Cell Leukemia/Lymphoma Virus (HTLV)," Proc. Natl. Acad. Sci. USA 80:5402-5406 (1983).	
		J.A. DIPAOLO et al., "Progressive Changes Induced in Human and Mouse Cells by Human Papillomavirus Type 16 DNA," Cancer Cells 5: 253-257 (1987).	
		M.K. PATTERSON, Jr., "Measurement of Growth and Viability of Cells in Culture," Methods Enzymol., 58:141-152 (1979).	
		L.H. THOMPSON, "Mutant Isolation," Methods Enzymol. 58: 308-322 (1979).	
		S. A. LATT et al., "Microfluorometric Detection of Deoxyribonucleic Acid Replication in Human Metaphase Chromosomes," Proc. Natl. Acad. Sci. USA 70:3395 (1973).	
		S. A. LATT, "Fluorometric Detection of Deoxyribonucleic Acid Synthesis; Possibilities for Interfacing Bromodeoxyuridine Dye," J. Histochem. Cytochem. 25:913-926 (1977).	
		P. PERRY& S. WOLFF, "New Giemsa Method for the Differential Staining of Sister Chromatids," Nature 261:156-158 (1974).	
		S. WOLFF (1981), "Measurement" in E.C. Friedberg & P.C. Hanawalt, eds., DNA Repair: A Laboratory Manual of Research, (Dekker, N.Y., 1981), vol. 1, Park B, pp. 575-586.	
		E.G. CORMIER et al., "CD81 Is an Entry Coreceptor for Hepatitis C Virus," Proc. Natl. Acad. Sci. USA 101:7270-7274 (2004).	

Examiner	Date	
Signature	Considered	

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Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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	te for form 1449/PTO		a or 1995, no persons a	Complete if Known		
				Application Number	10/574,163	
			CLOSURE	Filing Date	March 29, 2006	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	LIU, Jin	
	(Use as many she	ats as r	(Acassan)	Art Unit	TBD	
	(see do many ene		occasary)	Examiner Name	TBD	
Sheet	3	of	3	Attorney Docket Number	8028-005-US	

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue	T ²
		number(s), publisher, city and/or country where published.	'
		J.P. SALIER et al., "The Inter-•-Inhibitor Family: From Structure to Regulation," Biochem. J. 351: 1-9 (1996).	
		G. GRYNKIEWICZ et al, "A New Generation of Ca2+ Indicators with Greatly Improved Fluorescence Properties," J. Biol. Chem. 260:3440-3450 (1985).	
		E.J. STANBRIDGE et al, "Human Cell Hybrids: Analysis of Transformation and Tumorigenicity," Science 215:252-259 (1982).	
		T. TSURIMOTO et al., "Stable Expression and Replication of Hepatitis B Virus Genome in an Integrated State in a Human," Proc.Natl. Acad. Sci. USA 84:444-448 (1987).	
		C.A. BRENNER et al. "Message Amplification Phenotyping (MAPPing): A Technique to Simultaneously Measure Multiple mRNAs from Small," Biotechniques 7: 1096-1103 (1989).	
		Y.P. LIM et al., "Correlation Between Mortality and the Levels of Inter-alpha Inhibitors in Plasma of Severely Septic Patients," J. Infect. Dis. 188:919-926 (2003).	
		K. NAWA et al., "Glucocorticoid-Dependent Expression of the Albumin Gene in Adult Rat Hepatocytes," J. Biol. Chem. 261:16883-16888 (1986).	

Examiner	Date	
Signature	Considered	

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	Sara Hare
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June 15, 2006	SAR
Date of Deposit	Signature of Person Mailing Paper

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Examiner: To Be Assigned
Liu et al.) Group Art Unit: To Be Assigned
Serial No.: 10/574,163)) Docket No.: 8028-005-US
Filed: March 29, 2006) Date Mailed: June 15, 2006
For: IMMORTALIZED HEPATOCYTES)))

INFORMATION DISCLOSURE STATEMENT

Mail Stop: Information Disclosure Statement Honorable Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This document is an Information Disclosure Statement to the above-cited patent application.

Attached is at least one form PTO/SB/08A/B listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b), the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.96, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned at (858) 450-0099 x302 so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted within three months of the filing date of the above-identified patent application. Accordingly, no fee is due for the filing of this Information Disclosure Statement under 37 C.F.R. § 1.97(b)(1).

A copy of each document is enclosed, except for issued United States patents and published United States patent applications pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Some of the documents may have markings thereon. No significance is to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import, as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the prosecution of this application; and (2) represented on any patent which may issue on the application. Applicant respectfully

requests that copies of the forms PTO/SB/08A/B, as considered and initialed by the Examiner, be returned with the next communication.

- U.S. Patent No. 5,665,589 to Harris et al., issued on September 9, 1997.
- U.S. Patent No. 6,046,050 to Strauss et al., issued on April 4, 2000.
- U.S. Patent No. 6,107,043 to Jauregui et al., issued on August 22, 2000.
- U.S. Patent No. 6,653,105 to Triglia et al., issued on November 25, 2003.
- U.S. Patent Application Publication No. 2002/0045262 by Prachumsri, published on April 18, 2002.

PCT Patent Application Publication No. WO 99/55853 by Fukaya et al., published on November 4, 1999, which describes a novel immortalized hepatic cell line originating in normal human (preferably human fetal) cells, a process for producing this cell line; a method for screening compounds or salts thereof capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, the process involving using the above-mentioned cell line. The application further describes compounds capable of inhibiting or promoting the activity of an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of inhibiting or promoting the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, compounds capable of inhibiting or promoting the induction of the expression of a gene encoding an enzyme participating in the metabolism of a biological foreign matter in the liver, or salts of these compounds

obtained by the above screening method. The cell line is described as useful in, for example, screening compounds having preventive/therapeutic effects on liver failure.

A publication, J.B. Mills et al., "Induction of Drug Metabolism Enzymes and MDR1 Using a Novel Human Hepatocyte Cell Line," <u>J. Pharm. Exp. Therap.</u> 309: 303-309 (2003).

A publication, G. Luo et al., "CYP3A4 Induction by Drugs: Correlation Between a Pregnane X Receptor Reporter Gene Assay and CYP3A4 Expression in Human Hepatocytes," <u>Drug Metab.</u> Dispos. 30: 795-804 (2002).

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A publication, H. Zur Hausen, "Oncogenic Herpesviruses" in J. Tooze ed., <u>DNA Tumor Viruses</u> (Rev. Ed. 2, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1981), pp 747-795.

A publication, M. Popovic et al., "Transformation of Human Umbilical Cord Blood T-Cells by Human T-Cell Leukemia/Lymphoma Virus (HTLV)," <u>Proc. Natl. Acad. Sci. USA</u> 80:5402-5406 (1983).

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A publication, E.G. Cormier et al., "CD81 Is an Entry Coreceptor for Hepatitis C Virus," Proc. Natl. Acad. Sci. USA 101:7270-7274 (2004).

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A publication, T. Tsurimoto et al., "Stable Expression and Replication of Hepatitis B Virus Genome in an Integrated State in a Human Hepatoma Cell Line Transfected with the Cloned Viral DNA," Proc. Natl. Acad. Sci. USA 84:444-448 (1987).

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A publication, K. Nawa et al., "Glucocorticoid-Dependent Expression of the Albumin Gene in Adult Rat Hepatocytes," J. Biol. Chem. 261:16883-16888 (1986).

Respectfully submitted,

Date: Vune 15,2006

CATALYST LAW GROUP, APC 9710 Scranton Road, Suite 170 San Diego, California 92121 (858) 450-0099 (858) 450-9834 (Fax) Michael B. Farber, Ph.D., Esq. Registration Number: 32,612